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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/905,526 | 07/13/2001 | Sonya Merrill | ARC 2300N2 | 3977 |

27777 7590 04/07/2004
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EXAMINER

SHARAREH, SHAHNAM J

| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/905,526

Applicant(s)

MERRILL ET AL.

Examiner

Shahnam Sharareh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 55-312 is/are pending in the application.
- 4a) Of the above claim(s) 55-312 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 55-312 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/15/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on January 15, 2004 has been entered. Claims 1, 55-312 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the Amendment.

Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 of prior U.S. Patent No. 5,914,131. This is a double patenting rejection. The pending claims and the patented claims are directed to identical subject matter. Further, the scopes of both sets of claims are the same. Accordingly, claims are rejected under statutory double patenting-35 U.S.C 101 as they are directed to the same invention.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,11-14 of U.S. Patent No. 5,702,725 ('725) and claims 1-2 of U.S. Patent No. 5,529,787 ('787). Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons of record.

Election/Restrictions

Newly submitted claim 55-312 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: the newly added claim is directed to a distinct invention which is related as distinct products or distinct process of using the products.

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Each set of independent product claims, namely:

- claim 55 and dependent claims thereof,
- claim 72 and dependent claims thereof,
- claim 91 and dependent claims thereof,
- claim 117 and dependent claims thereof,
- claim 138 and dependent claims thereof,
- claim 152 and dependent claims thereof,
- claim 166 and dependent claims thereof,
- claim 194 and dependent claims thereof,
- claim 211 and dependent claims thereof,
- claim 245 and dependent claims thereof,
- claim 262 and dependent claims thereof,
- claim 279 and dependent claims thereof,
- claim 296 and dependent claims thereof, are directed to patentably distinct

products as they encompass various combinations of hydromorphone and a delivery system that could provide the desired property.

Each independent process of use claim, namely claims 89-90, 108-116, 136-137 may be practiced with materially different products.

Since none of the products are allowable, restriction is proper between claim 1 and the newly submitted products and method of use thereof. (MPEP, 806.05(I)).

Since applicant has received an action on the merits for the originally presented invention Group I, claims 1-45, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-312 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

This application contains claims 55-312 drawn to an invention nonelected with traverse in Paper No. 6/B. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RUSSELL TRAVERS
PRIMARY EXAMINER